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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,154

Applicant(s)

SKIFFINGTON ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-26 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 7-16 of Applicants' response, filed 29 April 2003, with respect to the rejection(s) of claim(s) 1-23 under 35 U.S.C. 251 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the references of Foote et al. (WO 95/25948) and Matsumoto et al. (JP 07-059555).

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application (US Provisional Application No. 60/001,081, filed 12 July 1995) upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-26 of this application. With respect to claim 1, the instant claim language of claim 1 recites that the unit dose reagent chamber is for detection of adenosine triphosphate (ATP) or alkaline phosphatase (AP) in a test sample. The specific reagents recited include one selected from the group consisting of i) a detergent-containing buffered solution to release adenosine triphosphate (ATP) or alkaline phosphatase (AP) from the test sample into solution; ii) a reaction stopping solution having a pH of 8 to 11; and iii) a luciferin-luciferase or phosphatase substrate reagent. The disclosure of U.S. Provisional Application No. 60/001,081, filed 12 July 1995, discloses unit dose reagent chambers that include a cylinder having a one open end and an other opposite open end and a probe-puncturable membrane seal over the one end and the other end of

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the cylinder to form a sealed compartment. Provisional Application 60/001,081 also discloses that i) a microbial lysis solution and ATP stabilizer can be a reagent held in the sealed chamber; ii) a buffer optimized for luciferin-luciferase reaction can be a reagent held in the sealed chamber; or iii) luciferin-luciferase reagent tablet can be a reagent held in the sealed chamber (See the first page of the disclosure and Figure 2). As a result, of all of the possible reagents listed in claim 1, U.S. Provisional Application 60/001,081 only provides support for "a luciferin-luciferase substrate reagent". Claims 2-13 depend from claim 1 and are not supported by the disclosure of U.S. Provisional Application No. 60/001,081 for the same reasons as set forth with respect to claim 1.

With respect to claim 14, the disclosure of U.S. Provisional Application No. 60/001,081 does not support the following claim limitations recited in claim 14: i) detection of alkaline phosphatase (AP) in a test sample; ii) by color; iii) a *transparent* test unit; iv) a first reagent composition to detect alkaline phosphatase by color; v) a second reagent for use in the detection of alkaline phosphatase; vi) reagent composition comprises a buffered solution to release adenosine triphosphate or alkaline phosphatase from the test sample. As recited with respect to claim 1 above, Provisional Application 60/001,081 only discloses the following reagents i) a microbial lysis solution and ATP stabilizer; ii) a buffer optimized for luciferin-luciferase reaction; or iii) luciferin-luciferase reagent tablet (See the first page of the disclosure and Figure 2). Claims 14-20 and 24 depend from claim 14 and are not supported by the disclosure of U.S. Provisional Application No. 60/001,081 for the same reasons as set forth with respect to claim 14.

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With respect to claim 21, the disclosure of U.S. Provisional Application No. 60/001,081 does not support the following claim limitations recited in claim 21: i) *transparent* test unit and ii) the one end having threads for attachment of the test unit to the test apparatus. Provisional Application 60/001,081 only discloses a test unit having an open end, a closed bottom end, a probe-puncturable membrane and one or more unit dose chambers wherein a chamber comprises a cylinder having a one open end and an other opposite open end; a probe-puncturable membrane seal over the one end and the other end of the cylinder to form a sealed compartment, and a reagent composition for use in the detection of a test sample and sealed within the sealed compartment. Claims 22, 23, 25 and 26 depend from claim 21 and are not supported by the disclosure of U.S. Provisional Application No. 60/001,081 for the same reasons as set forth with respect to claim 14.

Note claims 1-26 have benefit of the filing date of U.S. Provisional Application No. 60/007,585, filed 27 Nov. 1995, since these claims are supported by the disclosure of U.S. Provisional Application No. 60/007,585.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claim 21, line 11, "the test sample" lacks antecedent basis. It is suggested that the preamble of the claim be amended to recite a test sample (See independent claims 1 and 14). Claims 22, 23, 25 and 26 are indefinite because they depend from independent claim 21.

In claim 24, "said luciferase and said luciferin reagent" is indefinite because claim 14 from which claim 24 depends does not provide antecedent basis for "said luciferase and said luciferin reagent". Note it appears that claim 14 should depend from claim 19 since this claim provides the required antecedent basis.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Foote et al. (WO 95/25948).

For reasons stated in section 1) above, claim 1 does not have benefit of the filing date of U.S. Provisional Application 60/001,081. Claim 1 has an effective filing date of 27 Nov. 1995 because claim 1 has benefit of U.S. Provisional Application 60/007,585, filed 27 Nov. 1995. However, the reference of Foote et al. is available as prior art under 35 USC 102(a) since it has a publication date of 28 Sept. 1995.

With respect to claim 1, the reference of Foote et al. discloses unit dose chambers (12a, 12b, 12c) wherein each chamber is defined by a cylinder having two open ends sealed by probe-

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puncturable membrane seals (13a-13d). The reference discloses that the chambers include reagents necessary to detect ATP, i.e. extractants and reagents (See page 4, lines 6-24). The reference specifically recites luciferin-luciferase (see claim 4 of Foote et al.) as a bioluminescence agent contained in the dose chamber.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al.(WO 95/25948) in view of Bernstein (US 4,770,853).

The reference of Foote et al. has been discussed above.

While the reference of Foote et al. discloses the use of a probe-puncturable membrane and describes the membrane as "foil", the reference does not specifically recite the use of "aluminum foil".

The reference of Bernstein discloses that unit dose reagent chambers (15,20) are sealed with breakable membranes (7) made of aluminum foil (See column 6, lines 3-6).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ aluminum foil as the membrane material of the reference of Foote et al. for the known and expected result of providing a means recognized in the art for sealing a reagent chamber while being capable of being broken by a sample swab device.

11. Claims 3, 5, 6, 7, 10-14, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al.(WO 95/25948) in view of Wood (US 5,283,179).

Figure 1 of Foote et al. discloses a test apparatus including tube (1) and well member (3) attached to tube (1). Well member (3) of the test apparatus includes a bioluminescence reagent composition (8), wherein the reagent can be luciferin-luciferase (See claim 4). The test

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apparatus also includes an extracting agent (6) separated from the bioluminescence reagent by a probe-puncturable membrane (7).

While the extracting agent is separated from the bioluminescence reagent by membrane (7), instant claim 5 differs by reciting that the releasing or extracting reagent is provided in a unit dose chamber that includes an open-ended cylinder sealed by probe-puncturable membranes.

The reference of Foote et al. discloses that it may be desirable to keep the swab isolated from the lysis solution to keep it dry over a long period of time (See page 6, lines 10-22). The reference of Foote et al. also discloses that it is known in the art to provide the reagents in unit dose chambers (12a-12c) that include a cylinder sealed by breakable membranes (13a-13d).

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to provide the lysis reagent of the embodiment disclosed in Figure 1 of the reference of Foote et al. in a reagent compartment disclosed by Foote et al. for the known and expected result of isolating the lysis or extraction reagent from the swab prior to use and for allowing the device to be used in any orientation as suggested by the reference of Foote et al.

Claim 5 further differs by reciting that the extraction reagent is a detergent-containing buffered solution.

The reference of Wood discloses a lysing reagent known in the art that is a detergent-containing buffered solution and is compatible with luciferase assays (See column 16, lines 10-15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the lysis reagent disclosed by the reference of Wood in the device of the primary reference for the known and expected result of providing a means

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recognized in the art for lysing a sample for performing a luciferase assay. With respect to claim 3, the lysis reagent includes a phosphoric acid buffer (phosphate) and non-ionic detergent (Triton X-100) (See column 16, lines 10-15).

With respect to claims 6 and 11, the reference of Foote et al. discloses a longitudinally movable probe (4,5) to puncture the membrane seals (7, 13) and discloses that the longitudinal movement of the probe can be achieved by twisting or screwing (See page 5, lines 1-3).

With respect to claims 7 and 10, while the embodiment of Figure 1 discloses reagent (6) positioned within tube (1) rather than member (3), the embodiment of Figure 4 discloses that the reagent chambers can also be positioned in test unit (11).

In view of this disclosure and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide a sealed reagent chamber within member (3) rather than tube (1) for the known and expected result of providing an alternative means recognized in the art for providing reagents within a sealed chamber which are intended to be sequentially contacted with a probe member. Providing all of the reagents in member (3) would allow tube and probe member to be manufactured independent of the specific reagents employed.

With respect to claims 12 and 13, the reference of Wood discloses that it is known in the art to employ Tris in the lysing reagent and to employ tricine in the assay reagent (See column 16, lines 8-23).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ either Tris or tricine as buffers in the assay system for the known and expected result of employing reagents known in the art for performing a

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bioluminescence assay while maintaining or enhancing the activity of the enzymes (See column 8, lines 16-25).

With respect to claim 14, claim 14 includes a combination of the limitations of claims 5, 6 and 7 and is met by the combination of the references discussed above with respect to these claims.

With respect to claim 16, the lysis reagent includes a phosphoric acid buffer (phosphate) and non-ionic detergent (Triton X-100) (See column 16, lines 10-15 of Wood).

With respect to claim 19, see the discussion of claim 5 above.

12. Claims 8, 9, 17, 18, 21 and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al.(WO 95/25948) in view of Wood (US 5,283,179) taken further in view of Smola et al.(US 4,004,548).

The combination of the references of Foote et al. and Wood has been discussed above.

While the reference of Foote et al. discloses that member (3) is force-fit in the base of tube (1) (See page 4, lines 26-28), claims 8, 17, 21 and 23 differ by reciting that the test unit includes threads for attaching the test unit to the test apparatus.

The reference of Smola et al. discloses that it is known in the art that the use of screw threads for attachment of parts is an art recognized equivalent of a force-fit (See column 6, lines 49-52).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ screw threads on member (3) of the reference of Foote et al. for attachment to the tube (1) for the known and

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expected result of providing an alternative means recognized in the art to achieve the same result, attaching member (3) to tube (1). Use of screw threads would facilitate both assembly and disassembly of the device while maintaining a reliable connection of the two components.

With respect to the use of a probe-puncturable membrane to seal member (3) (claims 9, 18 and 21), the reference of Foote et al. employs membrane (7) to seal member (3). Additionally, the use of a membrane to seal the member would have been obvious for the known and expected result of providing a means recognized in the art for sealing a reagent containing vessel to protect its contents prior to use and for facilitating contacting the contents of the vessel with a sample or additional reagents when performing an assay. With respect to claim 23, claim 23 depends from claim 21 and the presence of a luciferin/luciferase reagent has already been discussed with respect to the rejection of claim 5.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al. (WO 95/25948) in view of Wood (US 5,283,179) taken further in view of Bernstein (US 4,770,853).

The combination of the references of Foote et al. and Wood has been discussed above.

While the reference of Foote et al. discloses the use of a probe-puncturable membrane and describes the membrane as "foil", the reference does not specifically recite the use of "aluminum foil".

The reference of Bernstein discloses that unit dose reagent chambers (15,20) are sealed with breakable membranes (7) made of aluminum foil (See column 6, lines 3-6).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ aluminum foil as the membrane material of the

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reference of Foote et al. for the known and expected result of providing a means recognized in the art for sealing a reagent chamber while being capable of being broken by a sample swab device.

14. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al. (WO 95/25948) in view of Wood (US 5,283,179) and Smola et al. (US 4,004,548) taken further in view of Bernstein (US 4,770,853).

The combination of the references of Foote et al., Wood and Smola et al. has been discussed above.

While the reference of Foote et al. discloses the use of a probe-puncturable membrane and describes the membrane as "foil", the reference does not specifically recite the use of "aluminum foil".

The reference of Bernstein discloses that unit dose reagent chambers (15,20) are sealed with breakable membranes (7) made of aluminum foil (See column 6, lines 3-6).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ aluminum foil as the membrane material of the reference of Foote et al. for the known and expected result of providing a means recognized in the art for sealing a reagent chamber while being capable of being broken by a sample swab device.

15. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al. (WO 95/25948) in view of Wood (US 5,283,179) taken further in view of Rich et al. (US 3,666,631).

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The combination of the references of Foote et al. and Wood has been discussed above.

While the reference of Foote et al. discloses the use of a freeze-dried bioluminescence reagent in member (3) (See page 4, line 20), claim 24 differs by reciting that the reagent is in tablet form.

The reference of Rich et al. discloses that it is known in the art to provide a luciferin/luciferase reagent in tablet form within a multiple chamber assay device (See column 4, lines 10-15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the freeze-dried reagent of the reference of Foote et al. in tablet form for the known and expected result of providing the required reagent in a form recognized in the art. Use of a tablet over a power would facilitate adding the reagent to the container since adding a tablet does not require measuring that is associated with the use of a power.

16. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al.(WO 95/25948) in view of Wood (US 5,283,179) and Smola et al.(US 4,004,548) taken further in view of Rich et al.(US 3,666,631).

The combination of the references of Foote et al., Wood and Smola et al. has been discussed above.

While the reference of Foote et al. discloses the use of a freeze-dried bioluminescence reagent in member (3) (See page 4, line 20), claim 24 differs by reciting that the reagent is in tablet form.

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The reference of Rich et al. discloses that it is known in the art to provide a luciferin/luciferase reagent in tablet form within a multiple chamber assay device (See column 4, lines 10-15).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the freeze-dried reagent of the reference of Foote et al. in tablet form for the known and expected result of providing the required reagent in a form recognized in the art. Use of a tablet over a power would facilitate adding the reagent to the container since adding a tablet does not require measuring that is associated with the use of a power.

17. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Foote et al.(WO 95/25948) in view of Wood (US 5,283,179) taken further in view of Abbas et al.(US 5,223,402).

The combination of the references of Foote et al. and Wood has been discussed above.

Claim 20 depends from claim 14 and differs by reciting that reagents are employed for releasing and detecting phosphatase from the sample.

The reference of Abbas et al. discloses that it is known in the art to detect for the presence of microorganisms using an assay that employs a releasing agent for releasing enzymes from the sampled microorganisms (See column 6, lines 41-43) and exposing the released enzymes to an alkaline phosphatase substrate to produce a color reaction (See column 5, lines 39-54, and column 8, lines 3-7).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the reagents disclosed by the reference of Abbas et al. in the system of the modified

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primary reference for the known and expected result of providing an alternative set of reagents recognized in the art for detecting microorganisms and producing a color reaction.

18. Claims 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al.(JP 07-59555) in view of Smola et al.(US 4,004,548).

The reference of Matsumoto et al. discloses a transparent test unit (1). The test unit has a closed bottom end and an open end closed by cover (6). The test unit also includes a unit dose chamber that includes a cylinder (2); probe-puncturable membranes (2a, 2b) creating a chamber holding a reagent (X) for detecting a test sample.

While the reference discloses the use of a cover (6) for the test unit, instant claim 21 differs by reciting that the test unit is sealed with a probe-puncturable membrane.

The reference of Matsumoto et al. discloses that the use of a probe-puncturable membrane (2a, 2b) is known in the art for sealing a chamber.

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to seal the open end of the test unit using an additional probe-puncturable membrane in place of cover (6) for the known and expected result of providing an alternative means recognized in the art for sealing a vessel. Use of the membrane would eliminate the need to remove cover (6) since probe device (4) would be capable of penetrating the membrane sealing the test unit.

While the reference of Matsumoto et al. discloses that member (7) is a force-fit connection relative to the open end of test unit (1) (See Figure 4), claim 21 differs by reciting that the test unit includes threads for attaching the test unit to the test apparatus.

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The reference of Smola et al. discloses that it is known in the art that the use of screw threads for attachment of parts is an art recognized equivalent of a force-fit (See column 6, lines 49-52).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ screw threads on the test unit (1) of the reference of Matsumoto et al. for attachment to member (7) for the known and expected result of providing an alternative means recognized in the art to achieve the same result, attaching test unit (1) to member (7). Use of screw threads would facilitate both assembly and disassembly of the device while maintaining the connection of the two components.

With respect to the use of a tablet of reagent, the reference of Matsumoto et al. discloses reagent (X) in liquid form while reagent (5) is in tablet form. In the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide reagent (X) in tablet form and reagent (5) as a liquid while maintaining the function of the assay device.

19. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al.(JP 07-59555) in view of Smola et al.(US 4,004,548) taken further in view of Bernstein (US 4,770,853).

The combination of the references of Masumoto et al. and Smola et al. has been discussed above.

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While the reference of Masumoto et al. discloses the use of a probe-puncturable membrane and describes the membrane as "film", the reference does not specifically recite the use of "aluminum foil".

The reference of Bernstein discloses that unit dose reagent chambers (15,20) are sealed with breakable membranes (7) made of aluminum foil (See column 6, lines 3-6).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ aluminum foil as the membrane material of the reference of Masumoto et al. for the known and expected result of providing a means recognized in the art for sealing a reagent chamber while being capable of being broken by a sample swab device.

Allowable Subject Matter

20. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

21. The following is a statement of reasons for the indication of allowable subject matter:

Claim 4 would be allowable because the prior art of record fails to teach or fairly suggest the claimed ATP or AP testing device that includes pH indicator in combination with the claimed releasing solution, reaction stopping solution, or luciferin-luciferase or phosphatase substrate reagent to detect the ATP or AD of a test sample and wherein the pH indicator does not materially affect the basic characteristics of any of the above listed compositions.


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Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB
July 18, 2003